DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: "Notification of Intent to Use Schedule III, IV, or V Controlled Medications for the Treatment of Opioid Use Disorder " Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234 and OMB No. 0930-0369) – Revision

The Drug Addiction Treatment Act of 2000 ("DATA," Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit qualifying practitioners to seek and obtain waivers to prescribe certain approved controlled medications for the treatment of opioid use disorder. The legislation set eligibility and certification requirements as well as an interagency notification review process for practitioners who seek waivers. To implement these provisions, SAMHSA developed Notification of Intent Forms that facilitate the submission and

review of notifications.

On October 24, 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Public Law 115-71) was signed into law. Sections 3201 – 3202 of the SUPPORT Act made several amendments to the Controlled Substances Act regarding office-based opioid use disorder treatment that affords practitioners greater flexibility in the provision of Medications for Opioid Use Disorder (MOUD).

The SUPPORT Act expands the definition of "qualifying other practitioner" enabling Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs) to apply for a Drug Addiction Treatment Act of 2000 (DATA) waiver. It also allows qualified practitioners (i.e., MDs, DOs, NPs, PAs, CNSs, CRNAs, and CNMs) who are board certified in addiction medicine or addiction psychiatry, -or- practitioners who provide MOUD in a qualified practice setting, to start treating up to 100 patients in the first year of MOUD practice (as defined in 42 CFR 8.2) with a waiver.

Further, the SUPPORT Act extends the ability to treat up to 275 patients to "qualifying other practitioners" (i.e., NPs, PAs, CNSs, CRNAs, and CNMs) if they have a waiver to treat up 100 patients for at least one year and provide MOUD with covered medications (as such terms are defined under 42 CFR 8.2) in a qualified practice setting as described under 42 CFR 8.615.

Finally, the SUPPORT Act also expands how physicians could qualify for a waiver. Under the statute now, physicians can qualify for a waiver if they have received at least 8 hours of training on treating and managing patients with opioid use disorder, as listed in the statute if the physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits a Notice of Intent to SAMHSA. In order to expedite the new provisions of the SUPPORT Act, SAMHSA sought and received a Public Health Emergency Paperwork Reduction Act Waiver.

On April 28, 2021 the Department of Health and Human Services (HHS) issued the new Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (86 FR 22439) in an expedited manner. The new Practice Guidelines allow practitioners who wish to obtain a 30-patient waiver to forego the 8-hour training requirement for physicians and 24-hour training for other qualifying practitioners. Practitioners utilizing this training exemption are limited to treating no more than 30-patients at a time and time spent practicing under this exemption will not qualify the practitioner to qualify for a higher patient level. In addition, the new Practice Guidelines removed the requirement to provide counseling and other ancillary services (i.e., psychosocial services).

The collection of information within the application is essential to the implementation of SAMHSA's mission to reduce the impact of substance use disorders on America's communities. Practitioners may use these forms for various types of notifications: (a) New Notification to treat up to 30 patients with training or without training; (b) New Notification, with the intent to immediately facilitate treatment of an individual (one) patient; (c) Second notification of need and intent to treat up to 100 patients; (d) New notification to treat up to 100 patients, and (e) New notification to treat up to 275 patients. The forms provide the information necessary to determine whether practitioners meet the qualifications for waivers set forth under the law at the 30E-, 30-, 100-, 275E-, and 275-patient limits. This includes the annual reporting requirements for practitioners with waivers for a 275-patient limit.

Under "new" notifications, practitioners may make their initial waiver requests to SAMHSA. "Immediate" notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). The form collects data on the following items: Practitioner name; state medical license number; medical specialty; and DEA registration number; address of primary practice location, telephone and fax numbers; e-mail address; purpose of notification: new, immediate, or renewal; certification of qualifying criteria for treatment and management of patients with opioid

use disorder; certification of capacity to provide directly or refer patients for appropriate counseling and other appropriate ancillary services, as applicable; certification of maximum patient load, certification to use only those medication formulations that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician and Behavioral Health Treatment Services locators. The following table summarizes the estimated annual burden for the use of this form.

42 CFR Citation	Purpose of Submission	Estimated Number of respondents	Responses/ Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)
	Notification of Intent	1,800	1	0.083	149
	Notification to Prescribe Immediately	60	1	0.083	5
	Notice to Treat up to 100 patients	600	1	0.04	24
	Notice to Treat up to 275 patients	960	1	0.081	78
	Subtotal	**3,420**	**-**	**-**	**256**
Burden Associated with the Final Rule That Increased the Patient Limit					
8.620 (a)-(c)	Request for Patient Limit Increase*	620	1	0.5	310
	Request for Patient Limit Increase*	620	1	0.5	310
	Request for Patient Limit Increase*	620	1	0.5	310
8.64	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
8.655	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	Subtotal	**2,497**	**-**	**-**	**1,279**

Burden Associated with the Final Rule That Outlined the Reporting Requirements					
8.635	Practitioner Reporting Form*	1,620	1	3	4860
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Nurse Practitioners	979	1	0.066	65
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Physician Assistants	708	1	0.066	47
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Specialists	708	1	0.066	47
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Mid-Wives	708	1	0.066	47
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Registered Nurse Anesthetists	708	1	0.066	47
	Sub Total	**5,431**		-	**5112**
	Total Burden	**6,561**	-	-	**6,647**

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-A, Rockville, Maryland 20857, ***OR*** e-mail a copy to **Carlos.Graham@samhsa.hhs.gov**. Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Carlos Graham,
Reports Clearance Officer.

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